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EXAMINER

BADR, HAMID R

ART UNIT	PAPER NUMBER
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1781

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/540,829	Applicant(s) BHASKAR ET AL.	
	Examiner HAMID R. BADR	Art Unit 1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/20/2011</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/20/2011 has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 10 is indefinite for "wherein the whey proteins are heat denatured at pH 6.0-7.0". The claim requires mixing high yield milk protein concentrate (HY-MPC) with liquid milk containing fat. The claim also requires that the whey protein be heat denatured. It is not clear whether the heat denaturation of whey proteins involves the liquid milk to which the HY-MPC is added or the heat denaturation of whey proteins is in reference to the HY-MPC, which already comprises heat denatured whey proteins.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Delespaul et al. (FR 2 452 879; Official Translation; hereinafter R1).

3. R1 teaches of heating the milk before the ultrafiltration process or heating the retentate of the ultrafiltration process to temperatures which can reach sterilization. This thermal treatment is effectuated at 75-150C and allows obtaining cheeses having fine and homogenous texture. R1 further explains that one can attribute the favorable effect of the heat treatment to partial denaturation of proteins or modification of the physical state of calcium present. (page 4, first and second paragraphs).

4. R1 teaches the decalcification of milk by ion exchange using cationic resins. Such resins can be charged for example by sodium, potassium, ammonium or hydrogen ion or by divalent ions such as magnesium, zinc, copper or trivalent ions depending on the salt concentration, pH and the desired composition of the material. (page 5, 3rd paragraph)

5. R1 discloses that the decalcification can be 0-80% and preferably 20-40%. The decalcification extent will depend on the type of cheese desired (page 7, second paragraph).

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6. R1 discloses that the decalcification is optionally associated with a heat treatment between 75-150C and preferably 90-110C. R1 restates that the decalcification together with heat treatment will allow obtaining a fine and homogenous texture of cheese. (page 7, 3rd paragraph). The heating of milk can be carried out before ultrafiltration or heating may be done on the retentate after ultrafiltering the milk. (page 4, first paragraph).

7. R1 discloses that the calcium can be reintroduced by adding a calcium salt or by mixing at least one non-decalcified product such as milk. (page 7, 4th, 5th and 6th paragraphs). It is therefore clear that the calcium depleted, heat treated milk product of R1 is mixed with milk or other materials containing calcium to make the mixture suitable for rennet coagulation due to the presence of calcium ions.

8. While R1 does not explicitly disclose a pH range at which whey proteins are heat denatured, the pH range as presently claimed is inherent to milk.

9. It is therefore clear that a heat denatured, calcium depleted milk protein concentrate (HY-MPC having calcium depletion at 0-80%) can be added to milk as required by Claim 10.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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11. Claims 1-9, 11-19 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhaskar et al. (WO 01/41578; of record, hereinafter R2) in view of Delespaul et al. (FR 2 452 879; Official Translation; of record, hereinafter R1) and Sanchelima (US 6,015,579; hereinafter R3)

12. R2 discloses the production of dried milk protein concentrates (MPC) which have been calcium depleted to an extent which allows improvements in the use of dried milk protein concentrates in cheese manufacture. The invention includes a method of cheese manufacture comprising a) dispersing in milk a dried MPC or MPI having at least 70% dry matter as milk proteins, b) treating the mixture with a coagulating enzyme to produce a curd, c) processing the curd to make cheese; Wherein the incorporation of calcium depleted MPC allows the manufacture of substantially nugget-free cheese. (Abstract).

13. R2 discloses the steps of incorporation of a dried MPC into milk and the subsequent cheese making process. (page 2, lines 8-15).

14. R2 discloses the extent of decalcification required as 20-100% depending on the milk protein content of the MPC. (page 2, lines 17-22)

15. R2 discloses the use of ion exchange, acidification and addition of chelating agents for the decalcification process. (page 3, lines 4-10).

16. R2 discloses the drying process which can be done by standard drying processes. Drying may be preceded by dewatering . (page 4, lines 31-34)

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17. R2 gives Examples of preparation of dried calcium depleted MPC (page 7) , the solubility of the dried product in water (page 9, Example 2), and processes for cheese preparation (page 9, Example 3).

18. R2 basically disclose most of technical features of the presently claimed invention, however, R2 is silent regarding the heat treatment of the raw material for decalcification.

19. The disclosure of R1 is incorporated by reference as cited above.

20. R1 discloses that the decalcification is optionally associated with a heat treatment between 75-150C and preferably 90-110C. R1 restates that the decalcification together with heat treatment will allow obtaining a fine and homogenous texture of cheese. (page 7, 3rd paragraph).

21. While R1 discloses the heating process together with decalcification of milk, R1 is silent regarding the incorporation of whey proteins into casein by heat treatment of milk to produce a high yield product as presently claimed.

22. R3 discloses a process for enhancing the incorporation of whey protein in the cheese curd. The process comprises heating the milk at 75-85C for 10 to 30 minutes. (Abstract). While R3 does not mention the pH of the milk being heated, a near neutral pH is inherent in the milk itself.

23. R3 discloses that the yield can be increased by incorporating whey proteins into the curd. (col. 3, lines 12-36)

24. It is noted that a heat process at greater than 100C for 4-15 minutes is being claimed (claim 7). It is also well known in the art that in heat processes; the temperature

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and the process time have inverse relationships. When a higher temperature is used, a shorter processing time is required to achieve a given effect. Therefore, it would be obvious to increase the temperature of R3's process meanwhile reducing the processing time. A higher temperature, shorter processing time would bring about a higher quality product regarding, color, flavor and other functional properties of the product.

25. In summary, R2 discloses the use of decalcified milk protein concentrate (MPC) in cheese making resulting in the production of nugget free cheese. R1 and R3 clearly teach of the effect of decalcification and heat treatment of the milk raw material in producing decalcified milk concentrate which can be coagulated by rennet and resulting in cheese with homogenous texture (i.e. nugget free cheese) and high yield due to incorporation of whey proteins into casein, respectively.

26. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the teachings of R2 for the production of a decalcified milk protein concentrate and increase the yield of the product by adopting the heating regimens of R1 and R3 which clearly disclose whey protein denaturation and its effect regarding the product yield. Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in preparing high yield calcium depleted milk concentrates and manufacturing cheese using the same.

Response to Arguments

Applicants arguments have been thoroughly reviewed. These arguments are not persuasive for the following reasons.

1. Applicants argue that the Examiner has not provided any evidence to counter the Declaration by Mr. Anema.

a. Delespaul (R1) clearly discloses the decalcification and heat treatment of milk products to make them suitable for cheese making. R1 further, teaches of the beneficial effect of decalcification and heat treatment of milk raw material on the homogenous texture of the cheese product.

2. Mr. Anema states that Delespaul does not provide any teaching in that regard because Delespaul uses ultrafiltration to remove water from the cheese milk to avoid the necessity for separating whey from casein. Thus Delespaul does not separate the whey and provides no reason to use reduced calcium MPC to prevent loss of whey protein in a traditional cheese making process.

a. Delespaul makes a milk protein concentrate (MPC) by employing ultrafiltration. Delespaul further teaches that the milk material can be heated and decalcified before or after concentration using ultrafiltration (page 4, first paragraph). Delespaul also clearly states the beneficial effect of heat treatment and decalcification of the milk material on the homogenous cheese texture. Therefore, since the method of Delespaul comprises both heat treatment and decalcification of the milk material, the prevention of loss of whey proteins would be intrinsic in the cheese made with the decalcified, heat treated milk material of Delespaul. One of ordinary skill in the art would realize that the temperature range taught by Delespaul denatures the whey proteins. Furthermore, as

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clearly disclosed by R3, this denaturation results in their association with caseins leading to improved cheese yield and thus the prevention of loss of these proteins in the whey separated from rennet curd.

3. Applicants argue that Delespaul does not disclose adding the ultrafiltration retentate or a calcium depleted MPC to a milk containing fat or any other aqueous solution used as the starting material in claim 10.

a. Delespaul prepares a concentrated milk product (by ultrafiltration) which has been heated and decalcified either before or after ultrafiltration process. Then Delespaul clearly states that “when the treatment leads to a total decalcification of the milk, of the retentate or other protein substances that can be coagulated by rennet, one again introduces a quantity of soluble calcium that is sufficient to allow the action of rennet and resulting coagulation.” Delespaul further states that “The calcium can be reintroduced by adding a calcium salt in appropriate proportions (for example, calcium chloride or monocalcium phosphate), OR MIXING AT LEAST ONE NON-DECALCIFIED PRODUCT CHOSEN FROM THE GROUP CONSISTING OF MILK.....and the proportions of non-decalcified and decalcified raw materials to be mixed ...” (page 7, paragraphs 3 and 4). Therefore, Delespaul anticipates mixing the heat treated milk protein concentrate with milk or any solution containing calcium as recited in claim 10, so that the mixture becomes suitable for coagulation with rennet.

b. There is no picking and choosing from different embodiments as alleged by Applicants.

4. Applicants argue that the Examiner has only provided conclusory reasoning for combining R2 and R1.

a. The rejection of claims 1 and 11 is an obviousness type rejection involving the teachings of Bhaskar (R2) in view of Delespaul (R1) and R3. As detailed above, the heat treatment of the raw material is disclosed by R1 resulting in denaturation of whey proteins leading to their association with caseins. This fact, intrinsic in the teachings of R1, is clearly disclosed by the newly added reference (R3) which discloses the association of whey proteins and casein upon heating the milk. R3 also discloses the heat processing would increase the yield of cheese. Therefore, the heating process is motivated and obvious in light of the teachings of R1 and R3.

Furthermore, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

It is agreed that Bhaskar (R2) does not disclose the heating process, but that is the reason why Delespaul and Sanchelima are cited. The teachings of R1 in view of R2 and R3 make the claimed invention obvious.

Applicants should also realize that the ultrafiltration process disclosed by Delespaul is in fact the process for making milk protein concentrate (MPC), and therefore, the heat treatment disclosed by Delespaul is a part of making the MPC which is later used for cheese making.

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5. Applicants argue that the denaturation of whey proteins and their association of casein leading to improved cheese yield and thus the prevention of loss of these proteins, has no basis in light of the teachings of R2 and R1.

a. R1 clearly teaches of a heating process at a temperature range which causes whey proteins denaturation as well known in the art. To further support this view, the new reference Sanchelima (R3) has been introduced.

6. Applicants argue that the expectation of decreased cold water solubility for heat treated MPC teaches away from incorporating the heat treatment step of R1 with the manufacturing process of R2.

a. R1 clearly discloses that the decalcification method is optionally associated with a thermal treatment of the raw material and that the combination of thermal treatment and the decalcification treatment makes it possible to obtain a fine and homogeneous texture of the cheese. (page 7, paragraph 3). Therefore, decalcification and heat treatment can be combined as disclosed by R1.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner
Art Unit 1781

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